

PROJECT STATUS:

A. Inactive (Must submit a closing summary)

- Study complete **and:**
- Inactive (no further contact with human subjects or data)
- Original data and/or research material have been destroyed
- The linkage between the existing data and original source of information has been destroyed
- Data with identifiers will be retained (indicate in a separate memorandum why such data will be retained, where and how long). **This requires an annual report on confidentiality measures**
- Project never initiated

B. Active (check all that apply)

- Study is active **and:**
- Currently enrolling subjects
- Subject enrollment complete
- Subjects in follow up phase(s)
- Data still being collected from records
 (study involves data abstraction only)
- Data still being collected from MDH agency (e.g. MCR, VSA, or Medicaid)
- Data analysis only (all data collected or (patients enrolled, all follow-up completed)

- C. Has there been any change in the procedures for protecting human subjects? Yes No
 (If yes, please explain in a separate memorandum and attach)
- D. Have there been any changes in the consent process (if applicable) Yes No
- E. Has there been any evidence either from your experience to date or from recent literature which indicate the existence of risks different from those previously described? Yes No (If yes, briefly describe in a separate memorandum and attach.)
- F. What is the total number of subjects you expect to recruit for this study? _____ (If this study does not involve subject recruitment (but data collection only) indicate with N/A)
- G. Number of subjects accrued this year? _____ (____ male ____ female)
 Since the study began? _____ (____ male ____ female)
- H. Has there been a withdrawal of any subjects from the research since your last review? Yes No
 (If yes, briefly describe in a separate memorandum and attach.)
- I. Have there been any complaints about the research? Yes No
 (If yes, briefly describe in a separate memorandum and attach.)

J. Have there been any SAEs (Serious Adverse Events)? Yes No (If yes, briefly describe in a separate memorandum and attach.)

K. If your study involves the collection of death certificates only provide the following information:

- Total number of death certificates received (from Maryland) this year _____
- Total number of death certificates received (from Maryland) since the study begin _____

L. Has this study been modified since the last review? Yes No
 If yes, was the modification (s) approved (by MDH) Yes No
 List all modifications approved during the last year and indicate MDH's IRB approval date for each (if more space is needed use a separate sheet of paper)

M. Are you requesting a modification with this review? Yes No (If yes, provide a complete description of the modification along with details regarding the need for the changes and indicate if the changes will affect the risk level of the study (or complete a request for modification form))

N. Have you published any articles (within the last year) resulting from this study? Yes No (If yes, provide citation below) If yes, have you provided copies to the Administration providing the data as well as to the IRB? Yes No (citation: _____)

*******DO NOT WRITE BELOW THIS LINE – IRB USE ONLY*******

- | | |
|--|---|
| <input type="checkbox"/> Protocol is as previously approved research may continue

<input type="checkbox"/> Protocol is approved as modified

<input type="checkbox"/> Protocol is as previously approved but risks have increased based on current knowledge, IRB full review completed and protocol approved

<input type="checkbox"/> Protocol is not adhering to proposal as approved, research must cease

<input type="checkbox"/> Study remains active for data analysis only

<input type="checkbox"/> Study never initiated | <input type="checkbox"/> Study complete, but data with identifiers will be retained and PI will continue to assure confidentiality and advise the IRB of any breach of confidentiality via annual report

<input type="checkbox"/> Study complete – data linkage destroyed

<input type="checkbox"/> Study has been modified and no longer qualifies as research, exempt from any further IRB review

<input type="checkbox"/> Study has been modified and qualifies as exempt research according to 45CFR46 101(b) _____ |
|--|---|

Signature _____
 Chair, MDH Institutional Review Board

Date _____